

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant: Steve Golden Examiner: Julian W. Woo
Serial No.: 10/715,797 Group Art Unit: 3773
Filed: November 18, 2003 Docket No.: P0021729.02 / M190.321.101
Due Date: May 12, 2009
Title: APPARATUS AND METHODS FOR ANASTOMOSIS

APPEAL BRIEF UNDER 37 C.F.R. §41.37

Mail Stop Appeal Brief – Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir/Madam:

This Appeal Brief is submitted in support of the Notice of Appeal filed on March 12, 2009, appealing the final rejection of claims 64, 66-75, and 123-141 of the above-identified application as set forth in the Final Office Action mailed December 12, 2008.

The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 50-0471 in the amount of \$540.00 for filing a Brief in Support of an Appeal (as set forth under 37 C.F.R. §41.20(b)(2)). At any time during the pendency of this application, please charge any required fees or credit any overpayment to Deposit Account No. 50-0471.

Appellant respectfully requests consideration and reversal of the Examiner's rejection of pending claims 64, 66-75, and 123-141.

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

REAL PARTY IN INTEREST

The real party in interest is Medtronic, Inc. of Minneapolis, Minnesota.

RELATED APPEALS AND INTERFERENCES

Appellant is unaware of other prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in this Appeal.

STATUS OF CLAIMS

In the Final Office Action mailed August 27, 2008, claims 64, 66-75, 123-132, 135-137, and 139-141 were rejected. Claims 133, 134 and 138 were objected to. Claims 76-81 were allowed. Claims 1-63, 65 and 82-122 are cancelled. Claims 64, 66-81, and 123-141 remain pending in the application and are the subject of the present Appeal.

STATUS OF AMENDMENTS

No Amendments have been filed subsequent to the Final Office Action mailed December 12, 2008.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The subject matter of the pending independent claims involved in the appeal relates to methods for performing an anastomosis while maintaining blood flow within a vessel.

Independent claim 64 recites one method of the pending application, and is generally explained at page 12, line 13 – page 16, line 14 and Figures 2-4, 7, and 11-14. The method includes positioning a piercing end (202, 502) of a cannula (200, 500) so that it pierces through a vessel wall (312), with the cannula (200, 500) being introduced into the vessel wall (312) from the interior of the vessel. A graft (G) is attached to the vessel wall (312) adjacent to the cannula (200) while the piercing end of the cannula (200, 500) extends through the vessel wall (312). The cannula (200, 500) is removed.

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

Independent claim 66 recites another method of the pending application, and is generally explained at page 16, line 15 – page 23; line 23; page 28, lines 7-27; and page 30, lines 26-27 and Figures 12-14, 15A-D, 16A-E, 17A-D, 18A-E, and 20A-20F. The method includes forming an opening in a wall of a blood vessel (714) and removing a portion of the wall (734) where the opening was formed. An occluding member (730, 800, 850, 900, 950) is inserted into the opening formed in the vessel and occludes the opening. Additionally, the method includes connecting a graft (712) to the vessel at the opening after the step of forming the opening and removing the wall portion (734).

Independent claim 123 recites another method of the pending application, and is generally explained at page 12, line 13 – page 16, line 14 and Figures 2-4, 7, and 11-14. The method includes positioning a cannula (200, 500) so that it extends through a vessel wall. In this regard, the cannula (200, 500) is introduced into the vessel wall from the interior of the vessel. More particularly, the cannula (200, 500) is passed through another portion of the vessel wall into the interior of the vessel and then from the interior of the vessel through the vessel wall. A graft (G) is attached to the vessel wall adjacent to the cannula (200, 500) while the cannula (200, 500) extends through the vessel wall. The method also includes removing the cannula (200, 500).

Independent claim 127 recites another method of the pending application, and is generally explained at page 14, line 17 – page 16, line 20 and Figures 6A-14. The method includes delivering a tubular member (602) having a first end and a second end into the interior of a vessel having a vessel wall. More particularly, the first end of the tubular member (602) is passed from the interior of the vessel through the vessel wall at a first vessel wall location. A graft (G) is attached to the first vessel wall location adjacent to the first end of the tubular member (602), and the tubular member (602) is removed.

Independent claim 128 recites another method of the pending application, and is generally explained at page 14, line 17 – page 23, line 23; page 28, lines 7-27; and page 30, lines 26-27 and Figures 6A-14, 15A-D, 16A-E, 17A-D, 18A-E, and 20A-20F. The method includes delivering a tubular member (602, 704, 704') having a first end and a second end into the interior

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

of a vessel having a vessel wall. The first end of the tubular member (602, 704, 704') is passed from the interior of the vessel through the vessel wall at a first vessel wall location. More particularly, tubular member (602, 704, 704') is passed through the vessel wall at a second location to deliver the first end of the tubular member (602, 704, 704') into the interior of the vessel before passing the first end of the tubular member (602, 704, 704') from the interior of the vessel through the vessel wall at the first vessel wall location. A graft (G, 712) is attached to an exterior of the vessel wall adjacent to the first end of the tubular member (602, 704, 704'), and the tubular member (602, 704, 704') is removed.

GROUNDΣ OF REJECTION TO BE REVIEWED ON APPEAL

I. First Grounds of Rejection

Whether claims 72 and 74 were properly rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

II. Second Grounds of Rejection

Whether claims 64, 123, 124, 125, and 127-131 were properly rejected under 35 U.S.C. §102(e) as being anticipated by LaFontaine et al., U.S. Patent No. 6,443,158 (“LaFontaine”).

III. Third Grounds of Rejection

Whether claims 66-74, 126, 132, 135-137, and 139-141 were properly rejected under 35 U.S.C. §102(e) as being anticipated by LeMole, U.S. Patent No. 5,893,369 (“LeMole”).

IV. Fourth Grounds of Rejection

Whether claim 75 was properly rejected under 35 U.S.C. §103(a) as being unpatentable over LeMole in view of Ho et al., U.S. Patent No. 6,514,265 (“Ho”).

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

ARGUMENT

I. APPLICABLE LAW

A. 35 U.S.C. § 112, Second Paragraph

Under 35 U.S.C. § 112, second paragraph, the claims must particularly point out and distinctly claim the subject matter which the Appellant regards as the invention. In evaluating a lack of antecedent basis, a claim is indefinite when it contains words or phrases whose meaning is unclear. *See MPEP §2173.05(e)*. The failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. *See MPEP §2173.05(e)* (citing *Energizer Holdings Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 77 USPQ2d 1625 (Fed. Cir. 2006) (*holding that "anode gel" provided by implication the antecedent basis for "zinc anode"*)); *Ex parte Porter*, 25 USPQ2d 1144, 1145 (Bd. Pat. App. & Inter. 1992).

B. 35 U.S.C. § 102(e)

With regard to the 35 U.S. C. § 102(e) anticipation rejection: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

C. 35 U.S.C. § 103(a)

Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. MPEP §2141. The examiner bears the burden under 35 U.S.C. §103 in establishing a *prima facie* case of obviousness. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

articulated reasoning with some additional rational underpinning to support the legal conclusion of obviousness.” *KSR Int'l Co. v. Teleflex, Inc.*, 82 USPQ2d 1385, 1396 (US 2007); *In re Khan*, 78 USPQ2d 1329 (Fed. Cir. 2006). In this regard, identification of a teaching, suggestion, or motivation for modifying a reference or combination of the teachings of multiple references provides helpful insight. *KSR* at 1396. “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Leapfrog Enterprises, Inc. v. Fischer-Price, Inc.*, 82 USPQ2d 1687, 1690-1691 (Fed. Cir. 2007). A prior patent cited as a §103 reference must be considered in its entirety, “i.e., as a whole, including portions that lead away from the invention.” *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1597 (Fed. Cir. 1987). That is, the examiner must recognize and consider not only the similarities, but also the critical differences between the claimed invention and the prior art as one of the inquiries pertinent to any obvious inquiry under 35 U.S.C. §103. *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990).

II. The rejections of Claims 72 and 74 under 35 U.S.C. §112, second paragraph, as being indefinite are improper and should be reversed.

In rejecting claims 72 and 74 as being indefinite, the Office Action regards “said anastomosing” as lacking antecedent basis. First, Appellant believes that the Office Action contains a typographical error, and claims 71 and 74 are the rejected claims, since claim 72 does not contain “said anastomosing.” With this, claims 71 and 74 both ultimately depend from claim 66 which relates to a method for performing an anastomosis on a vessel wall while maintaining blood flow within the vessel. To one skilled in the art, “performing an anastomosis” has discernable meaning as “anastomosing.” As such, Appellant respectfully requests reversal of the rejection under 35 U.S.C. §112, second paragraph.

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

III. The rejections of Claims 64, 123, 124, 125, and 127-131 under 35 U.S.C. §102(e) as being anticipated by LaFontaine are improper and should be reversed.

LaFontaine relates to a system and method for percutaneous coronary artery bypass through a venous vessel. Initially, and as shown in FIG. 3, proximal and distal ends of a restriction 22 in a coronary artery 16 are located. An elongate portion or tubular member 58 of a cutting device 56 is inserted into the artery 16 (FIG. 5A); steered outwardly through a wall of the artery 16 and into a vein 20 (FIG. 5B); and then steered outwardly through the wall of the vein 20, through a wall of the artery 16, and back into the artery 16 (FIG. 5D). Subsequently, the tubular member 58 is removed, leaving only a guide wire 66 as shown in FIG. 5E. An introducer 88/90 carrying a graft 86 is then fed over the guide wire 66 and along the previously cut path through and between the artery 16 and the vein 20, resulting in the arrangement of FIG. 6C. Ends of the graft 86 are then secured to an interior of the artery 16 via stents 94, 96. With this understanding of LaFontaine in mind, it is respectfully submitted that the rejections of independent claims 64, 123, 127, and 128 based on LaFontaine should be reversed.

A. Independent Claim 64 is Not Anticipated by LaFontaine

With respect to independent claim 64, claim 64 recites positioning a cannula through a vessel wall and attaching a graft to the vessel wall adjacent the cannula. In rejecting claim 64, the Final Office Action identifies the cutting device 56/tubular member 58 of LaFontaine as being the claimed "cannula". While the tubular member 58 may or may not constitute a cannula, LaFontaine clearly describes that the tubular member 58 is entirely removed prior to deploying and attachment of the graft 86. For example, as shown in FIG. 5E of LaFontaine, the tubular member 58 (FIGS. 5A and 5B) has been removed. LaFontaine further discloses that a graft 86 may either be inserted after the cutting device 56 is withdrawn (FIG. 5E) or concurrently with the cutting device 56. The graft is inserted via an introducer advanced over the guide wire 66, in which case at least the tubular member 58 would necessarily be removed prior to inserting the graft. Thus, use of the tubular member 58 in accordance with the disclosure of LaFontaine does

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

not teach positioning a cannula and attaching a graft adjacent to the cannula while the cannula extends through the vessel wall, as otherwise set forth in claim 64.

In addition, claim 64 recites that a piercing end of the cannula pierces through the vessel wall, and that the graft is attached to the vessel wall adjacent the piercing end. As described above, use of the tubular member 58 of LaFontaine does not teach these features. Further, the introducer 88/90 does not have a piercing end, and deployment of the introducer 88/90 does not include piercing through vessel wall. Instead, any “piercing” accomplished with the methodology of LaFontaine is provided solely through use of the cutting device 56/tubular member 58. Thus, the disclosure of LaFontaine relative to use of the introducer 88/90 does not teach every feature of claim 64. For at least these reasons, then, it is respectfully submitted that the rejection of claim 64, as well as claims 124 and 125 depending thereon, should be reversed.

B. Independent Claim 123 is Not Anticipated by LaFontaine

With respect to independent claim 123, the Office Action’s reference to LaFontaine’s use of the tubular member 58 does not teach the “attaching a graft to the vessel wall adjacent to said cannula while said cannula extends through said vessel wall” features of claim 123 as described above with respect to claim 64. In addition, claim 123 recites that the cannula is passed through another portion of the vessel wall into the interior of the vessel, and then from the interior vessel through the vessel wall. LaFontaine discloses an opposite methodology. In particular, LaFontaine describes the introducer 88/90 passing from the interior of the vessel 16 and through the vessel wall (i.e., FIG. 6B), followed by passage of the introducer 88/90 from the exterior of the vessel 16, through the vessel wall, and into the vessel interior (FIG. 6C). In other words, claim 123 recites passing the cannula through the vessel wall and into an interior of the vessel, followed by extension through the vessel wall from the interior (e.g., exterior to interior passage, followed by interior to exterior extension); in contrast, LaFontaine teaches interior to exterior passage, followed by exterior to interior extension. For at least these reasons, then, it is respectfully submitted that claim 123 is allowable over LaFontaine.

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

C. Independent Claim 127 is Not Anticipated by LaFontaine

Independent claim 127 recites passing a first end of a tubular member from an interior of a vessel through a wall of the vessel at a first vessel wall location. Claim 127 further recites that a graft is attached to the first vessel wall location adjacent the first end of the tubular member. As described above, the tubular member 58 of LaFontaine is removed prior to attachment of the graft 86, and thus use of the tubular member 58 cannot teach the “attachment” features of claim 127. Further, FIG. 6C illustrates the stent 94 associated with the graft 86 as being spaced from the vessel wall location at which the introducer 88/90 passes through the vessel 16 wall. The stent 94 defines the location at which the graft 86 is attached to the vessel 16. In light of the discrete arrangement of the stent 94 relative to the vessel wall location at which the introducer 88/90 passes through, the methodology of LaFontaine does not teach “attaching a graft to the first vessel wall location” of claim 127. For at least these reasons, independent claim 127, as well as claims 129-131 depending thereon, are allowable over LaFontaine.

D. Independent Claim 128 is Not Anticipated by LaFontaine

Independent claim 128 recites that a tubular member is initially passed through a vessel wall at a second location to deliver a first end of the tubular member into an interior of the vessel before passing the first end of the tubular member from the interior through the vessel wall at a first vessel wall location. LaFontaine is in direct opposition. More particularly, LaFontaine passes the tubular member 58 (as well as the introducer 88/90) from an interior to an exterior of the vessel 16, followed by passage from the exterior to the interior. In other words, claim 128 recites exterior to interior passage, followed by interior to exterior passage; LaFontaine discloses interior to exterior passage, followed by exterior to interior passage. In addition, claim 128 recites attaching a graft to an exterior of the vessel wall. In contrast, FIG. 6E of LaFontaine teaches attachment of the graft 86 to the interior of the vessel 16 wall. For at least these reasons, it is respectfully submitted that claim 128 is allowable over LaFontaine.

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

IV. The rejections of Claims 66-74, 126, 132, 135-137, and 139-141 under 35 U.S.C. §102(e) as being anticipated by LeMole is improper and should be reversed.

With respect to independent claim 66, claim 66 recites that a graft is connected to a vessel at an opening formed in the vessel after the step of forming the opening and removing a portion of the vessel wall. In contrast, FIGS. 5 and 6 of LeMole clearly show that the graft 14 is connected to the vessel 12 prior to formation of an opening in the vessel wall (and/or removing a portion of the wall where the opening was formed). FIGS. 7 and 8 further illustrate that the opening in the vessel 12 wall is formed (and a wall portion removed) subsequent to connection of the graft 14. Further, as noted in the Final Office Action, the graft of LeMole is positioned at a first opening and then attached at a second location, being some other point distinct from the first opening. For at least these reasons, then, it is respectfully submitted that claim 66, as well as claims 67-74, 126, 132, 135-137, and 139-141 depending thereon, are allowable over LeMole.

V. The rejection of Claim 75 under 35 U.S.C. §103(a) as being unpatentable over LeMole in view of Ho et al., U.S. Patent No. 6,514,265 (“Ho”) is improper and should be reversed.

With respect to the rejection of claim 75 based on LeMole in view of Ho, Appellant incorporates by reference the above noted arguments. Claim 75 depends from and further defines independent claim 66 which is believed allowable for the reasons noted above. As such, claim 75 is allowable over the cited references for at least the reasons noted above.

CONCLUSION

Based on the arguments above, claims 64, 66-75, and 123-141 (as well as allowed claims 76-81) are allowable over the cited prior art. Appellant submits that the Examiner has presented the best available references against the claimed subject matter of the pending application. Reversal of the rejections of claims 64, 66-75, and 123-141 is respectfully requested.

Any inquiry regarding this Appeal Brief should be directed to either Katrina Witschen at Telephone No. (763) 505-8418, Facsimile No. (763) 505-8436 or Timothy A. Czaja at

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

Medtronic CardioVascular

7000 Central Avenue

Minneapolis, MN 55432

Respectfully submitted,

Steve Golden,

By their attorneys,

DICKE, BILLIG & CZAJA, PLLC

Fifth Street Towers, Suite 2250

100 South Fifth Street

Minneapolis, MN 55402

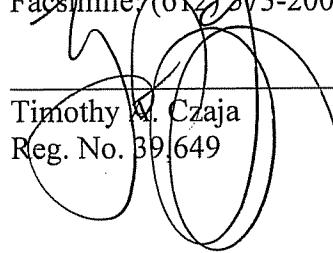
Telephone: (612) 573-2004

Facsimile: (612) 573-2005

Date: May 12, 2009

TAC:jms

Timothy A. Czaja
Reg. No. 39,649



Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

CLAIMS APPENDIX

1. – 63.(Cancelled)

64. A method for performing an anastomosis while maintaining blood flow within a vessel comprising:

positioning a piercing end of a cannula so that it pierces through a vessel wall, wherein the cannula is introduced into the vessel wall from the interior of the vessel;
attaching a graft to the vessel wall adjacent to said cannula while said piercing end of said cannula extends through said vessel wall; and
removing the cannula.

65.(Cancelled)

66. A method for performing an anastomosis on a vessel wall while maintaining blood flow within the vessel comprising:

forming an opening in a wall of a blood vessel and removing a portion of the wall where the opening was formed;
inserting an occluding member into the opening formed in the vessel and occluding the opening therewith; and
connecting a graft to the vessel at the opening after the step of forming an opening and removing a portion of the wall.

67. The method of claim 66, wherein said forming an opening comprises: piercing the vessel wall with a piercing member extending from a shaft; and

cutting the opening in the vessel wall around the piercing member shaft with a cutting tool.

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

68. The method of claim 67, further comprising removing a tissue plug produced by said cutting, prior to said inserting an occluding member.

69. The method of claim 67, wherein said inserting comprises inserting the occluding member into the opening cut into the vessel while the cutting tool is still in the opening.

70. The method of claim 69, further comprising withdrawing the cutting tool to allow the occluding member to expand against the periphery of the opening, thereby occluding it.

71. The method of claim 70, further comprising placing a graft over the occluding member and in alignment with the opening, prior to said anastomosing.

72. The method of claim 67, further comprising sliding a generally circular centering disk along the piercing member shaft onto the vessel wall, prior to said cutting, thereby clamping vessel wall tissue between the centering disk and a portion of the piercing member.

73. The method of claim 72, further comprising removing the clamped vessel wall tissue between the centering disk and the portion of the piercing member.

74. The method of claim 66, wherein said anastomosing comprises fastening walls of the graft and vessel together using fasteners.

75. The method of claim 74, wherein said fastening is performed with self closing fasteners.

76. A method for performing an anastomosis on a vessel wall while maintaining blood flow within the vessel comprising:

forming an opening in a wall of a blood vessel and removing a portion of the wall where the opening was formed;

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

inserting an occluding member into the opening formed in the vessel and occluding the

opening therewith; and

anastomosing a graft to the vessel at the opening;

wherein the occluding member includes fasteners attached thereto and the fasteners have

needles coupled thereto, said method further comprising expanding the occluding

member and pulling back said occluding member and piercing the vessel wall

with the needles coupled to said fasteners.

77. A method for performing an anastomosis on a vessel wall while maintaining blood flow within the vessel comprising: forming an opening in a wall of a blood vessel; inserting an occluding member into the opening formed in the vessel to occlude the opening with the occluding member; and anastomosing a graft to the vessel at the opening; wherein the occluding member includes fasteners attached thereto and the fasteners have needles coupled thereto, said method further comprising pulling back said occluding member to pierce the vessel wall with the needles; further comprising grasping the needles and pulling them entirely through the vessel wall, thereby positioning the fasteners for performing the anastomosis and separating them from the occluding member.

78. The method of claim 77, wherein the fasteners each have a second needle at an end opposite the location of the needles used to pierce the vessel wall, said anastomosing further comprising piercing the graft with the second needles and securing the graft and the vessel together by closing the fasteners upon them.

79. A method for performing an anastomosis on a vessel wall while maintaining blood flow within the vessel comprising: forming an opening in a wall of a blood vessel; inserting an occluding member into the opening formed in the vessel to occlude the opening; and anastomosing a graft to the vessel at the opening; wherein said forming an opening comprises: piercing the vessel wall with an anchor member and cutting the opening in the vessel wall around

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

the anchor member with a cutting tool; wherein an adapter is mounted on the cutting tool, the adapter retaining a plurality of needles therein which are prepositioned for piercing the vessel from the inside out, said method further comprising inserting the cutting tool and adapter into the vessel, prior to said inserting an occluding member, so as to position the needles against the inner wall of the vessel, and pulling back the adapter and cutting tool to pierce the vessel wall with the needles; grasping the needles and pulling them all the way through the vessel and thereby also removing them from the adapter.

80. The method of claim 79, wherein the needles are connected to two-stage release fasteners having independently closable first and second portions, the needles being connected by flexible members to respective first portions of the fasteners, said method further comprising removing the needles and flexible members from the fasteners, after insertion of the occluding member, thereby closing the first portions of the fasteners and fixing the fasteners to the wall of the vessel.

81. The method of claim 80, wherein the fasteners each have a second needle connected to an end portion of the second portion thereof by a second flexible member, said anastomosing further comprising piercing the graft with the second needles and securing the graft and the vessel together by removing the second needles and second flexible members from the second portions of the fasteners, thereby closing the second portions of the fasteners on the graft and fixing the walls of the vessel and the graft in approximation.

82. – 122.(Cancelled)

123. A method for performing an anastomosis while maintaining blood flow within a vessel comprising:

positioning a cannula so that it extends through a vessel wall, wherein the cannula is introduced into the vessel wall from the interior of the vessel;

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

attaching a graft to the vessel wall adjacent to said cannula while said cannula extends

through said vessel wall; and

removing the cannula;

wherein the cannula is passed through another portion of the vessel wall into the interior of the vessel and then from the interior of the vessel through the said vessel wall.

124. The method of claim 64 wherein the cannula is delivered endovascularly through the vessel.

125. The method of claim 64 wherein the cannula forms an area of hemostasis.

126. The method of claim 66 wherein said occluding member comprises a cannula.

127. A method for performing an anastomosis comprising:

delivering a tubular member having a first end and a second end into the interior of a vessel having a vessel wall;

passing the first end of the tubular member from the interior of the vessel through the vessel wall at a first vessel wall location;

attaching a graft to the first vessel wall location adjacent to the first end of the tubular member; and

removing the tubular member.

128. A method for performing an anastomosis comprising:

delivering a tubular member having a first end and a second end into the interior of a vessel having a vessel wall;

passing the first end of the tubular member from the interior of the vessel through the vessel wall at a first vessel wall location;

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

attaching a graft to an exterior of the vessel wall adjacent to the first end of the tubular member; and

removing the tubular member

wherein the tubular member is passed through the vessel wall at a second location to deliver the first end of the tubular member into the interior of the vessel before passing the first end of the tubular member from the interior of the vessel through the vessel wall at the first vessel wall location.

129. The method of claim 127 wherein the tubular member is delivered endovascularly through the vessel.

130. The method of claim 127 wherein the tubular member forms an area of hemostasis.

131. The method of claim 127 wherein the tubular member comprises a cannula.

132. The method of claim 66 wherein said occluding member is radially expandable.

133. The method of claim 132 wherein said occluding member comprises a plurality of wires having a memory shape.

134. The method of claim 133 further including a restraint to releasably hold the plurality of wires in a shape that differs from said memory shape.

135. The method of claim 132 wherein said occluding member comprises an expandable membrane.

136. The method of claim 135 wherein said expandable membrane is an inflatable member.

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

137. The method of claim 135 further including a sheath extending over a portion of said occluding member.

138. The method of claim 132 wherein said occluding member comprises a plurality of expansion members and a membrane between the expansion members.

139. The method of claim 132 wherein said occluding member forms an umbrella.

140. The method of claim 132 wherein said occluding member comprises a flexible sealing member.

141. The method of claim 140 further including a restraining sheath slidably mounted to the flexible sealing member for restraining the flexible sealing member and withdrawing the restraining sheath to expand the occluding member.

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

EVIDENCE APPENDIX

All the evidence related to this Appeal is on the record and before the Board. Therefore, no additional evidence is identified in this Appendix.

Appeal Brief to the Board of Patent Appeals and Interferences

Appellant: Steve Golden

Serial No.: 10/715,797

Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

RELATED PROCEEDINGS APPENDIX

There are no additional related proceedings to be considered in this Appeal. Therefore, no such proceedings are identified in this Appendix.